Complete Summary

GUIDELINE TITLE

Diabetic foot disorders: a clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, Landsman AS, Lavery LA, Moore C, Schuberth JM, Wukick DK, Andersen C, Vanore JV. Diabetic foot disorders: a clinical practice guideline. J Foot Ankle Surg 2006 Sep-Oct;45(5):S2-66. [579 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons. J Foot Ankle Surg 2000;39(5 Suppl):S1-60. [248 references]

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Diabetic foot ulcers
- Diabetic foot infections
- Diabetic Charcot foot

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Infectious Diseases
Internal Medicine
Nephrology
Nursing
Orthopedic Surgery
Podiatry
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Podiatrists

GUIDELINE OBJECTIVE(S)

To present clinical practice guidelines on the diagnosis, treatment, management, and prevention of diabetic foot disorders

TARGET POPULATION

Patients with diabetes mellitus who have or who are at risk of developing diabetic foot disorders

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and Evaluation

1. History (global history, foot-specific history, wound/ulcer history)
2. Clinical examination (vascular, neurologic, musculoskeletal, dermatologic, footwear)
3. Diagnostic procedures:
    - Laboratory testing as indicated
    - Imaging studies (x-rays and other studies as indicated)
    - Vascular procedures (noninvasive arterial studies)
    - Neurologic procedures (e.g., Semmes-Weinstein monofilament)
    - Plantar foot pressure assessment
4. Risk stratification

Prevention

1. Multidisciplinary team approach
2. Patient and family education
3. Regular podiatrist visits
4. Therapeutic shoes
5. Provider education

Management/Treatment of Diabetic Foot Ulcers

1. Management of comorbidities
2. Evaluation of vascular status
3. Assessment of lifestyle/psychosocial factors
4. Ulcer assessment and evaluation
5. Tissue management/wound bed preparation
    - Debridement (surgical/sharp), including control of moisture balance, wound dressing, and assessment of inflammation and infection
    - Pressure relief/off-loading
6. Management of wounds that fail to heal

Management/Treatment of Diabetic Foot Infections

1. Treatment for non-limb threatening infection
    - Antibiotics
    - Cleaning and debridement
2. Treatment for limb-threatening infection
    - Surgical treatment (debridement, draining, open amputation)
    - Antibiotic therapy
    - Microbiologic/histopathologic assessment of bone

Management/Treatment of Charcot Foot

1. Immobilization/stress reduction
2. Progression to weightbearing
3. Special footwear
4. Reconstructive surgery

Prevention of Foot Complications

1. Podiatric care
2. Protective shoes
3. Pressure reduction
4. Prophylactic surgery
5. Preventive education

MAJOR OUTCOMES CONSIDERED

- Incidence and morbidity of diabetic foot disorders
- Rates of limb salvage and/or diabetic limb amputations
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This clinical practice guideline is based on the consensus of current clinical practice and review of the clinical literature.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Assessment Of The Diabetic Foot (Pathway 1)

The pedal manifestations of diabetes are well documented and potentially limb-threatening when left untreated. Recognition of risk factors and treatment of diabetic foot disorders require the skill of a specialized practitioner to diagnose, manage, treat, and counsel the patient. Integration of knowledge and experience through by a multidisciplinary team approach promotes more effective treatment, thereby improving outcomes and limiting the risk of lower extremity amputation.

The evaluation of the diabetic foot involves careful assimilation of the patient's history and physical findings with the results of necessary diagnostic procedures (see Pathway 1 in the original guideline document). Screening tools may be valuable in evaluating the patient and determining risk level (see Appendix 1 in the original guideline document). Early detection of foot pathology, especially in high-risk patients, can lead to earlier intervention and thereby reduce the potential for hospitalization and amputation. This is also facilitated by an understanding of the underlying pathophysiology of diabetic foot disorders and associated risk factors. Identification of abnormal historical and/or physical findings can therefore improve the prognosis for a favorable outcome through appropriate—and early—referral.

History

A thorough medical and foot history must be obtained from the patient. The history should address several specific diabetic foot issues (see the Table below).

Table. Medical History		
Global History	**Foot Specific History**	
	General	**Wound/Ulcer History**
• Diabetes - duration • Glycemic management/control • Cardiovascular, renal, and ophthalmic evaluations • Other comorbidities • Treating physicians • Nutritional status • Social habits: alcohol, tobacco, drugs • Current medications • Allergies • Previous hospitalizations/surgery	• Daily activities, including work • Footwear • Chemical exposures • Callus formation • Foot deformities • Previous foot infections, surgery • Neuropathic symptoms • Claudication or rest pain	• Location • Duration • Inciting event or trauma • Recurrences • Infection • Hospitalization • Wound care • Off-loading techniques • Wound response • Patient compliance • Interference with wound care (Family or social problems for patient) • Previous foot trauma or surgery • Presence of edema-unilateral vs. bilateral • Charcot foot – previous or active • Charcot treatment

Physical Examination

All patients with diabetes require a pedal inspection whenever they present to any health care practitioner, and they should receive a thorough lower extremity examination at least once annually. Patients with complaints relating to the diabetic foot require more frequent detailed evaluations. The examination should be performed systematically so that important aspects are not overlooked. It begins with a gross evaluation of the patient and extremities. Any obvious problem can then receive closer scrutiny.

Key components of the foot examination are presented in Table 3 of the original guideline document. Although not specifically mentioned, it is assumed that a general medical assessment (including vital sign measurements) will be obtained.

Diagnostic Procedures

Diagnostic procedures may be indicated in the assessment and care of the diabetic foot. Consideration should be given to the following tests in concert with members of the consulting team. It should be noted that many of the following tests lack the ability to impart a definitive diagnosis, necessitating clinical correlation.

Laboratory Tests

Clinical laboratory tests that may be needed in appropriate clinical situations may include: fasting or random blood glucose, glycohemoglobin (HbA1C), complete blood count (CBC) with or without differential, erythrocyte sedimentation rate (ESR), serum chemistries, C-reactive protein, alkaline phosphatase, wound and blood cultures, and urinalysis. Caution must be exercised in the interpretation of laboratory tests in these patients, because several reports have documented the absence of leukocytosis in the presence of severe foot infections. A common sign of persistent infection is recalcitrant hyperglycemia despite usual antihyperglycemic regimens.

Imaging Studies

The diabetic foot may be predisposed to both common and unusual infectious or noninfectious processes, partially because of the complex nature of diabetes and its associated vascular and neuropathic complications. As a result, imaging presentations will vary due to lack of specificity in complex clinical circumstances. Such variability creates a challenge in the interpretation of imaging studies. Therefore, imaging studies should only be ordered to establish or confirm a suspected diagnosis and/or direct patient management. Distinguishing osteomyelitis from aseptic neuropathic arthropathy is not easy, and all imaging studies (see Figure 4 in the original guideline document) must be interpreted in conjunction with the clinical findings.

Plain radiographs should be the initial imaging study in diabetic patients with signs and symptoms of a diabetic foot disorder. Radiographs can detect osteomyelitis, osteolysis, fractures, dislocations seen in neuropathic arthropathy, medial arterial calcification, soft tissue gas, and foreign bodies as well as structural foot deformities, presence of arthritis, and biomechanical alterations. Acute osteomyelitis might not demonstrate osseous changes for up to 14 days. Serial radiographs should be obtained in the face of an initial negative radiographic image and a high clinical suspicion of osseous disease.

See the original guideline document for a discussion of other imaging studies, including technetium bone scans, white blood cell scintigraphy, computed tomography (CT), magnetic resonance imaging (MRI), positive emission tomography (PET) scanning, and ultrasound.

Vascular Evaluation

The lower extremity must be assessed for vascular and neuropathic risk factors. Although positive findings in the neurologic examination rarely require further evaluation, positive findings of vascular insufficiency may require further consultation. The indications for vascular consultation include an ankle brachial index of less than 0.7, toe blood pressures less than 40 mmHg, or transcutaneous oxygen tension ($TcPO_2$) levels less than 30 mmHg, since these measures of arterial perfusion are associated with impaired wound healing.

If the history and physical examination suggest ischemia (i.e., absent pedal pulses) or if a nonhealing ulcer is present, further evaluation in the form of

noninvasive testing is warranted (see Pathway 2 in the original guideline document).

Noninvasive arterial studies (NIAS) should be performed to determine lower extremity perfusion. Such studies may include Doppler segmental arterial pressures and waveform analysis, ankle-brachial indices (ABI), toe blood pressures, and $TcPO_2$.

Vascular consultation should be considered in the presence of abnormal noninvasive arterial studies or a nonhealing ulceration. Arteriography with clearly visualized distal runoff allows appropriate assessment for potential revascularization. Magnetic resonance angiography (MRA) or CT angiogram are alternatives for evaluation of distal arterial perfusion.

Neurologic Evaluation

Peripheral sensory neuropathy is the major risk factor for diabetic foot ulceration. The patient history and physical examination utilizing the 5.07 Semmes-Weinstein monofilament (10-g) wire are sufficient to identify those individuals at risk for ulceration.

Vibration perception threshold assessment with the biothesiometer is also useful in identifying patients at high risk for ulceration. More sophisticated studies, such as nerve conduction studies, are rarely necessary to diagnose peripheral sensory neuropathy. Patients with neuropathic ulcerations will usually have such profound sensory neuropathy that these studies add little to their clinical management.

Plantar Foot Pressure Assessment

High plantar foot pressure is a significant risk factor for ulceration. Measurement of high plantar foot pressure is possible utilizing a variety of modalities. Several computerized systems can provide quantitative measurement of plantar foot pressure. While these measurements may be important in identifying areas of the foot at risk for ulceration and possibly in evaluating orthotic adjustments, they are primarily used in diabetic foot research. The Harris mat, while not as sophisticated, can provide a qualitative measurement of plantar foot pressures and can identify potentially vulnerable areas for ulceration.

Risk Stratification

Following a thorough diabetic foot examination, the patient may be classified according to a cumulative risk category. This enables the physician to design a treatment plan and determine whether the patient is at risk for ulceration or amputation. Several risk stratification schemes have been proposed, assigning different weights to important risk factors for ulceration including peripheral neuropathy, arterial insufficiency, deformity, high plantar pressures, and prior history of ulceration or amputation. Although no one system has been universally adopted to predict complications, Table 4 in the original guideline document presents a simplified risk stratification that has been endorsed by an international consensus group and others.

The Healthy Diabetic Foot: Prevention Strategies

A healthy, intact diabetic foot is best maintained by a consistent and recurrent preventive treatment strategy. This is best accomplished through a multidisciplinary approach involving a team of specialists and personnel who provide a coordinated process of care (see Figure 5 in the original guideline document). Team members may include a podiatrist, internist, ophthalmologist, endocrinologist, infectious disease specialist, cardiologist, nephrologist, vascular surgeon, orthopedic surgeon, nurse (educator, wound care, and home care), and pedorthist/orthotist.

Patient and family education assumes a primary role in prevention. Such education encompasses instruction in glucose assessment, insulin administration, diet, daily foot inspection and care, proper footwear, and the necessity for prompt treatment of new lesions. Regularly scheduled podiatric visits, including debridement of calluses and toenails, are opportunities for frequent foot examination and patient education. Such visits can provide early warning of impending problems and subsequent modification of activity and care.

Diabetes is a lifelong problem, and the incidence of diabetic foot complications increases with age and duration of the disease. A recent Markov analysis of the cost effectiveness of foot care according to published guidelines found that such preventive care can improve survival, reduce ulceration and amputation rates, is cost-effective, and can even save on long-term costs when compared with standard care.

Risk stratification based on the presence of predisposing causal risk factors, including prior history of ulceration, also serves as a guide to the frequency of foot care visits. By identifying high-risk patient and tailoring a total foot care prevention program accordingly, the incidences of ulceration and lower extremity amputations can be reduced.

Therapeutic shoes with pressure-relieving insoles and high toe boxes are important adjunctive treatments that can reduce the occurrence of ulceration and resultant amputation in high-risk patients. While most studies support the efficacy of protective footwear in this regard, two reports suggest that shoes in the absence of a comprehensive prevention program might not be sufficient to prevent new lesions. Nevertheless, patients with foot deformities that cannot be accommodated by standard therapeutic footwear should have custom shoes that provide appropriate fit, depth, and a rocker insole. If structural deformities cannot be accommodated by therapeutic footwear, prophylactic surgical correction should be considered, but patients must be carefully selected.

Diabetic patients at risk for foot lesions must be educated about risk factors and the importance of foot care, including the need for self-inspection and surveillance, monitoring foot temperatures, appropriate daily foot hygiene, use of proper footwear, good diabetes control, and prompt recognition and professional treatment of newly discovered lesions. Home temperature assessment of the foot has been shown to reduce the incidence of foot ulcers 10-fold compared with standard preventive care. Patients with visual or physical impairments that preclude their own care should engage the assistance of family or friends to aid in this regard. When combined with a comprehensive approach to preventive foot

care, patient education can reduce the frequency and morbidity of limb threatening diabetic foot lesions.

Provider education is equally important in prevention, since not all clinicians are cognizant of important signs and risk factors for pedal complications. Furthermore, provider education is effective in reinforcing proper diabetes management and foot care practices, resulting in reductions in ulceration and adverse lower extremity outcomes.

Pathologic Entities Of The Diabetic Foot (Foot Ulcer, Infection, Charcot Foot)

Effective management of diabetic foot disorders requires knowledge of the potential pathologies, the associated classification systems and the principal tenets of intervention. Ulceration, infection, and Charcot arthropathy are the most significant of these pathologies, and classification systems have been developed for each entity. While the conditions may be seen either as an isolated event or coexisting in the same extremity, each entity is examined independently in this clinical practice guideline.

Diabetic Foot Ulcers (Pathway 3)

Evaluation of Ulcers

The initial evaluation of the diabetic foot ulcer must be comprehensive and systematic to ascertain the parameters that might have led to its onset as well as determine the presence of factors that can impair wound healing. Critical in this regard are assessments for vascular perfusion (ischemia), infection/osteomyelitis, and neuropathy. As previously discussed, a thorough vascular evaluation must be performed; this includes palpation of pulses, clinical evaluation of capillary filling time, venous filling time, pallor on elevation, and dependent rubor. If pulses are not palpable or if clinical findings suggest ischemia, noninvasive arterial evaluation (e.g., segmental Doppler pressures with waveforms, ankle brachial indices, toe pressures, $TcPO_2$ measurements) and vascular surgical consultation are warranted. When required, these physiologic and anatomic data can be supplemented with the use of MRA or CT angiography (CTA) and subsequent use of arteriography with digital subtraction angiography (DSA) as necessary.

Description of the ulcer characteristics on presentation is essential for the mapping of the ulcer's progress during treatment. While some characteristics are more important than others, they all have a prognostic value during management. The presumed etiology of the ulcer (i.e., chemical vs. mechanical) and character of the lesion (neuropathic, ischemic, or neuroischemic) should be determined. The evaluation should also describe the size and depth of the ulcer, as well as the margins, base, and geographic location on the extremity or foot. All but the most superficial ulcers should be examined with a blunt, sterile probe. The description should note whether the sterile probe detects sinus tract formation, undermining of the ulcer margins, or dissection of the ulcer into tendon sheaths, bone, or joints. A positive probe to bone (PTB) finding is highly predictive of osteomyelitis, although the frequency of false-negative tests reduces its sensitivity. Perhaps most importantly, the positive predictive value for PTB falls off significantly when the prevalence of osteomyelitis decreases.

The existence and character of odor or exudate should be noted. Cultures may be necessary when signs of inflammation are present. Generally, clinically uninfected ulcers without inflammation should not be cultured. Current recommendations for culture and sensitivity include thorough surgical preparation of the wound site with curettage of the wound base for specimen or with aspiration of abscess material.

Classification of Ulcers

Appropriate classification of the foot wound is based on a thorough assessment. Classification should facilitate treatment and be generally predictive of expected outcomes. Several systems of ulcer classification are currently in use in the US and abroad to describe these lesions and communicate severity. Perhaps the easiest system is to simply classify the lesions as neuropathic, ischemic, or neuroischemic, with descriptors of wound size, depth, and infection. Regardless of which system is used, the clinician must be able to easily categorize the wound and, once classified, the ensuing treatment should be directed by the underlying severity of pathology. Refer to the original guideline document for descriptions of the following classification systems: Wagner system; University of Texas San Antonio (UTSA) system; and the PEDIS (perfusion, extent/size, depth/tissue loss, infection, and sensation) system.

Imaging studies play an important role in the assessment and evaluation of the diabetic foot ulcer. Plain x-rays are indicated based on the extent and nature of the ulcer. Clinical change in the appearance of the ulcer or failure to heal with appropriate treatment may dictate repeating the radiograph periodically to monitor for osseous involvement. Additional imaging modalities such as nuclear medicine scans, ultrasonography, MRI, and CT may be indicated depending on the clinical picture.

Figure 6 in the original guideline document summarizes the important elements of the overall assessment of the patient with a diabetic foot ulcer. The assessment addresses underlying pathophysiology, possible causal factors, and significant predictors of outcome.

Treatment of Diabetic Ulcers: Guiding Principles

The primary treatment goal for diabetic foot ulcers is to obtain wound closure as expeditiously as possible. Resolving foot ulcers and decreasing the recurrence rate can lower the probability of lower extremity amputation in the diabetic patient.

The essential therapeutic areas of diabetic ulcer management are as follows: management of comorbidities; evaluation of vascular status and appropriate treatment; assessment of lifestyle/psychosocial factors; ulcer assessment and evaluation; tissue management/wound bed preparation; and pressure relief.

Management of Comorbidities

Because diabetes is a multi-organ systemic disease, all comorbidities that affect wound healing must be assessed and managed by a multidisciplinary team for optimal outcomes in the diabetic foot ulcer. Many systemic manifestations affect

wound healing. Among the most common comorbidities are hyperglycemia and vascular diseases such as cerebral vascular accidents, transient ischemic attacks, myocardial infarctions, angina, valvular heart disease, atrial fibrillation, aneurysms, renal dysfunction, hypertension, hypercholesterolemia, and hyperlipidemia.

Evaluation of Vascular Status

Arterial perfusion is a vital component for healing and must be assessed in the ulcerated patient, since impaired circulation contributes significantly to nonhealing of ulcers and subsequent risk for amputation. Early evaluation and referral are important. Symptoms of vascular insufficiency may include edema, altered skin characteristics (lack of hair, diseased nails, altered moisture), slow healing, cool or cold extremities, and impaired arterial pulsation. Vascular reconstructive surgery of the occluded limb improves prognosis and may be required prior to debridement, foot sparing surgery, and partial amputation.

Assessment of Lifestyle/Psychosocial Factors

Lifestyle and psychosocial factors may influence wound healing. For example, smoking has a profound effect on wound healing due to its associated vasoconstriction and low oxygen-carrying capacity of blood. Other factors (e.g., alcohol and drug abuse, eating habits, obesity, malnutrition, and mobility and activity levels) should also be noted. In addition, depression and mental illness may impact the outcome of treatment, since these conditions can directly affect the patient's adherence to recommendations and attitude towards healing.

Ulcer Assessment and Evaluation

The importance of a thorough and systematic evaluation of any ulceration cannot be overemphasized; indeed, the findings of an ulcer-specific examination will directly guide subsequent treatment. Initial evaluation and detailed description of any ulcer should encompasses location, size, depth, shape, inflammation, edema, exudate (quality and quantity), past treatment, and duration. The margins of the ulcer should be assessed for callus formation, maceration, and erythema. The presence of erythema along with other signs such as tenderness and warmth might suggest infection. The quality of the tissue (i.e., moist, granular, desiccated, necrotic, undermining, slough, eschar, or liquefied) should be noted. Thorough evaluation is used to determine the presence of sinus track or deep abscess.

Frequent re-evaluation with response-directed treatment is essential. Once the ulcer is healed, management consists of decreasing the probability of recurrence.

Tissue Management/Wound Bed Preparation

<u>Debridement</u>

Debridement of necrotic tissue is an integral component in the treatment of chronic wounds since they will not heal in the presence of unviable tissue, debris, or critical colonization. Undermined tissue or closed wound spaces will otherwise

harbor bacterial growth. Debridement serves various functions: removal of necrotic tissue and callus; reduction of pressure; evaluation of the wound bed; evaluation of tracking and tunneling; and reduction of bacterial burden. Debridement facilitates drainage and stimulates healing. However, debridement may be contraindicated in arterial ulcers. Additionally, except in avascular cases, adequate debridement must always precede the application of topical wound healing agents, dressings, or wound closure procedures. Of the five types of debridement (surgical, enzymatic, autolytic, mechanical, and biological) only surgical debridement has been proven to be efficacious in clinical trials.

Surgical Debridement

Surgical debridement is the cornerstone in the management of diabetic foot ulcers. Thorough sharp debridement of all nonviable soft tissue and bone from the open wound is accomplished primarily with a scalpel, tissue nippers, curettes, and curved scissors. Excision of necrotic tissue extends as deeply and proximally as necessary until healthy, bleeding soft tissue and bone are encountered. Any callus tissue surrounding the ulcer must also be removed. The main purpose of surgical debridement is to turn a chronic ulcer into an acute, healing wound. A diabetic ulcer associated with a deep abscess requires hospital admission and immediate incision and drainage. Joint resection or partial amputation of the foot is necessary if osteomyelitis, joint infection, or gangrene is present. The principles guiding the surgical management of diabetic foot ulcers are discussed under "Surgical Management of the Diabetic Foot," below.

Necrotic tissue removed on a regular basis can expedite the rate at which a wound heals and has been shown to increase the probability of attaining full secondary closure. Less frequent surgical debridement can reduce the rate of wound healing and secondarily increase the risk of infection. Surgical debridement is repeated as often as needed if new necrotic tissue continues to form. Frequent debridement, referred to as "maintenance debridement," is commonly required. While the terms surgical debridement and sharp debridement are often used synonymously, some clinicians refer to surgical debridement as that done in an operating room whereas sharp debridement is performed in a clinic setting.

Hydrosurgery (Versajet ®, Smith & Nephew, Inc., London, UK) is a novel system indicated for the surgical debridement of damaged and necrotic tissue in traumatic, ulcerated, and chronic wounds, surgical incisions, and burns. Among its properties are precision, selective cutting, and minimal thermal damage to the tissues.

When surgical or sharp debridement is not indicated, other types of debridement can be used. For example, vascular wounds may benefit from enzymatic debridement, while an extremely painful wound may benefit from autolytic debridement. Mechanical debridement is often used to cleanse wounds prior to surgical or sharp debridement. In areas where the medical staff is not trained in surgical or sharp debridement, these other forms of debridement may be useful. See the original guideline development for information about these other types of debridement.

Moisture Balance

One of the major breakthroughs in wound management over the past 50 years was the demonstration that moisture accelerates re-epithelialization in a wound. Tissue moisture balance is a term used to convey the importance of keeping wounds moist and free of excess fluids. A moist wound environment promotes granulation and autolytic processes. Effective management of chronic wound fluids is an essential part of wound bed preparation; it also helps in addressing the issues of cellular dysfunction and biochemical imbalance.

Wound dressings can be categorized as passive, active, or interactive. Passive dressings primarily provide a protective function. Active and interactive dressings and therapies are capable of modifying a wound's physiology by stimulating cellular activity and growth factor release. A wide variety of wound care products is available; a brief listing of dressing and topical agents is presented in Table 8 in the original guideline document.

Inflammation and Infection

In chronic wounds, inflammation persists due to recurrent tissue trauma and the presence of contaminants. Nonhealing wounds can become "stuck" in the inflammatory phase of healing, increasing cytokine response with subsequent elevated protease levels and impaired growth factor activity. The presence of infection must be ascertained and identified as local (soft tissue or osseous), ascending, and/or systemic. In diabetes, where the host response is reduced and normal signs of infection (i.e., fever, pain, leukocytosis) may be absent, other factors such as elevated glucose levels can be helpful as an indicator of infection. It is important to obtain specimens for culture prior to antimicrobial therapy. Tissue specimens collected by curettage or biopsy are preferred, because they provide more accurate results than superficial swabs.

Advanced Wound Care Modalities

Wound bed preparation offers clinicians a comprehensive approach to removing barriers to healing and stimulating the healing process so that the benefits of advanced wound care can be maximized. Advanced care may sometimes be the only means of rapidly and effectively attaining wound closure. The advent of therapeutic growth factors, gene therapy, tissue-engineered constructs, stem cell therapy, and other drugs and devices that act through cellular and molecular-based mechanisms is enabling the modern surgeon and wound-care provider to actively promote wound angiogenesis to accelerate healing.

See the original guideline document for further discussion of advanced wound care modalities, as well as a discussion of adjunctive modalities, such as regenerative tissue matrix, hyperbaric oxygen therapy, ultrasonic therapy, negative pressure wound therapy, and electrical stimulation.

Pressure Relief/Off-loading

The reduction of pressure to the diabetic foot ulcer is essential to treatment. Proper off-loading and pressure reduction prevents further trauma and promotes healing. This is particularly important in the diabetic patients with decreased or absent sensation in the lower extremities. Furthermore, recent studies provide evidence that minor trauma (e.g., repetitive stress, shoe pressure) plays a major

role in the causal pathway to ulceration. A list of off-loading modalities is presented in Figure 8 of the original guideline document.

The choice of off-loading modality should be determined by the patient's physical characteristics and ability to comply with the treatment, as well as by the location and severity of the ulcer. Various health care centers prefer specific initial modalities, but frequently clinicians must alternate treatments based upon clinical progress of the wound.

Regardless of the modality selected, no patient should return to an unmodified shoe until complete healing of the ulcer has occurred. Furthermore, any shoe that resulted in the formation of an ulcer should never again be worn by the patient.

Wounds That Fail to Heal

Wounds that do not respond to appropriate care, including debridement, off-loading, and topical wound therapies, must be reassessed. Infection and ischemia are especially important considerations and common reasons for failure to heal.

The presence of infection must be determined and identified as either soft tissue, osseous, or both. Excessive bioburden can be indicated by pale or friable granulation tissue, persistent drainage, or fibrinous surface layer. Indicators for frank infection will also include pain (especially in the neuropathic patient), erythema, and induration. When bone or joint is visible or palpable at the depth of the ulcer, osseous infection becomes more likely. A thorough discussion of the management of infected wounds is presented later in this document and summarized in Pathway 4 in the original guideline document.

Unrecognized ischemia will also impair wound healing and must be diagnosed prior to development of infection or ischemic necrosis of the ulcer. When no progress or enlargement of the wound has taken place, re-examination of the vascular status of the extremity is warranted (see Pathway 2 in the original guideline document). This should include arterial Doppler segmental pressures with waveforms, digital arterial pressures, or measurement of transcutaneous oxygen partial pressures (TcPO2). Vascular surgical consultation should also be considered for further evaluation and treatment.

Other parameters critical to wound healing should also be addressed, including the need for further debridement or a change in off-loading modality. Nonadherence to prescribed treatments or off-loading can be especially problematic in patients with peripheral neuropathy. Additional concerns may include renal insufficiency, biochemical imbalances, chronic anemia, nutritional deficiencies, or ulceration due to nondiabetic etiologies (i.e., radiation, malignancy, etc). Biopsy of chronic, nonhealing wounds should always be considered. Table 9 in the original guideline document summarizes the range of possible impediments to wound healing.

Diabetic Foot Infections (Pathway 4)

Foot infection is a major reason for hospitalization among patients with diabetes and also an important causal factor for lower limb amputation. There are various

presentations of diabetic foot infections as well as several ways to classify these entities.

Classification of Diabetic Foot Infections

Foot infections may be described in terms of severity, extent of involvement, clinical appearance, location, and etiology. Any system for classifying these infections should also serve to facilitate management and predict outcomes. One well accepted method simply provides two categories: non-limb-threatening or limb-threatening infections. This scheme implies severity of infection and, accordingly, directs subsequent management while also portending a general prognosis for outcome.

Patients with non-limb-threatening infections are medically stable and usually do not present with signs and symptoms of systemic involvement. This relatively mild to moderate infection can be managed on an outpatient basis, with close supervision from the clinician.

For limb-threatening infections, hospitalization is required in order to treat the infection as well as systemic sequelae. Patients with poor vascular status and ischemia have an increased potential for amputation and require prompt consultation for potential revascularization.

See Table 10 in the original guideline for the Infectious Disease Society of America's guidelines for the clinical classification of diabetic foot infections.

Assessment of Diabetic Foot Infections

When evaluating the patient with a diabetic foot infection, a problem-directed history and physical examination should be obtained. A systematic approach to the complete assessment of these patients is required since there is evidence that they are often inadequately evaluated even when hospitalized. The past medical history should assess the patient's neurologic, cardiovascular, renal, and dermatologic status. Use of current medications as well as previous antibiotics may interfere with planned treatments or indicate that standard treatments will likely be ineffective. Pain should be considered an unreliable symptom in individuals with peripheral neuropathy. The patient should be questioned regarding previous ulcerations, infections, trauma, and surgeries at the present site or any other past location of infection.

Constitutional symptoms (e.g., nausea, malaise, fatigue, vomiting, fever, chills) are important clinical clues when presented with an infected diabetic foot. Severe infection or sepsis must be considered when these symptoms are present. However, in about 50% of diabetic patients presenting with significant infection, systemic signs (fever and leukocytosis) are absent. Frequently, the only indication of infection is unexplained or recalcitrant hyperglycemia. Laboratory testing might include a complete blood count with or without differential, blood cultures, glycosylated hemoglobin, fasting blood sugar, sedimentation rate, and urinalysis. Other tests should be performed as indicated by the patient's condition or comorbidities.

The history of the wound or infection should include the onset, duration, and appearance before infection of the area. Depth or size of the ulcer, amount of drainage, swelling, color, odor, and extent of infection should be evaluated. The infection or ulcer should be probed to determine the presence of bone or joint involvement, sinus tracts, or extension into tendon sheaths. The latter are common routes for the spread of infection both distally and proximally. Reliable aerobic and anaerobic cultures should be obtained from purulent drainage or curettage of the ulcer base, since studies have shown good concordance with the true pathogen. Simple swab cultures of an ulcer surface are generally not advisable because they tend to be unreliable, especially in the presence of osteomyelitis or sinus tracts.

For patients with clinically uninfected or noninflamed neuropathic ulcers, the role of antibiotic therapy is still in question. Therefore, in these instances, wound culture is probably unnecessary. If osteomyelitis is suspected, bone cultures are necessary to make the definitive diagnosis and isolate the true pathogen. However, this must be balanced against the possibility of contaminating noninfected bone in the presence of an active soft-tissue infection. Intraoperative frozen section is also useful in assessing for deep infection. The presence of more than 5 to 10 neutrophils per high power field is suggestive of acute infection.

Imaging studies are also important in the overall assessment of diabetic foot infections, notwithstanding their shortcomings. Plain-film x-rays may indicate the presence of bony erosions and/or gas in the soft-tissues. It should be noted that the demonstration of osteomyelitis by plain radiographs lags the onset of bone involvement by 10 to 14 days. Radionuclide bone scans such as technetium-99 (Tc-99) may demonstrate abnormal uptake of the radionucleotide before changes are visible on radiographs. This may be less specific in patients with peripheral neuropathy or with any pre-existing osseous condition that causes increased bone turnover (e.g., surgery, fracture, neuropathic arthropathy). A combination of scans such as the Tc-99m and an indium-labeled leukocyte scan, or the Tc-99m-hexamethylpropyleneamine oxime (HMPAO)-labeled leukocyte scan may aid the clinician in differentiating Charcot arthropathy and osteomyelitis with greater accuracy. MRI has generally supplanted the CT scan in the early diagnosis of osteomyelitis (see Figure 10 in the original guideline document) due to its higher tissue contrast and ability to detect both soft-tissue and marrow inflammation. Additionally, MRI can be used to follow the resolution of infection or as an aid in surgical planning. However, none of the aforementioned imaging modalities are 100% sensitive and specific for diagnosing or ruling out bone infection. Furthermore, these tests are expensive and may not be readily available. Appropriate clinical assessment and diagnostic acumen should therefore remain the guiding principles to management.

Treatment of Diabetic Foot Infections

Diabetic foot infections should be managed with a multidisciplinary team approach utilizing appropriate consultations. Hospitalization of patients with limb-threatening infections is mandatory. All diabetic foot infections must be monitored closely. Equally important for the best possible outcome are patient compliance and education, especially in outcome management.

Treatment of Non-Limb-Threatening Infections

Treatment of diabetic foot infections is guided by the severity of the infection. As previously discussed, non-limb-threatening infections involve superficial ulcerations without significant ischemia and they do not involve bone or joint. Typically, cellulitis does not extend 2 cm beyond the ulcer margins and there is an absence of systemic symptoms (e.g., fever, chills, nausea, vomiting). These less severe infections that frequently complicate diabetic foot ulcers may be initially treated in an outpatient setting. Many mild or moderate infections are monomicrobial, with *Staphylococcus aureus, Staphylococcus epidermidis*, and streptococci being the most common pathogens. Reliable specimens for cultures may be obtained through curettage of the infected ulcer. In addition to the standard treatment for ulcerations (i.e., nonweightbering and dressing changes), oral antibiotic therapy is usually sufficient as initial therapy (see Table 11 in the original guideline document). Antimicrobial treatment should be started as soon as possible with an agent providing adequate gram-positive coverage, recognizing that gram-negative organisms might also be involved. Although the incidence of methicillin-resistant *S. aureus* (MRSA) infections has increased dramatically in the past several years, methicillin-sensitive *S. aureus* (MSSA) remains the most likely pathogen in community-acquired diabetic foot infections. Therefore, initial antibiotic coverage must be tailored to cover MSSA, unless a reliable culture and sensitivity is available or there is a history of other pathogens (e.g., MRSA, *Pseudomonas*, enterococcus) that require specific coverage. Antibiotics should be adjusted according to culture results and the patient's response to treatment.

All antibiotic treatments should be monitored for development of resistance. Most cases of cellulitis respond within 3 to 5 days of initiation of appropriate antibiotics. If cellulitis is slow to respond, worsens, or recurs following several days of treatment, the ulceration should be reassessed and possibly recultured. Bacteria frequently develop resistance to an antimicrobial agent, especially with prolonged therapy. This is not uncommon with the quinolones. Superinfection can also develop when antibiotics select out opportunistic organisms, as in the case of *Pseudomonas* or yeast (*Candida sp*). Because MRSA infections have become increasingly more common pathogens and are associated with prior antimicrobial exposure, patients with clinical infection and a prior history of MRSA should be considered to have the same pathogen until proven otherwise and treated accordingly.

Antimicrobial therapy alone is not sufficient for treating infections associated with foot ulcers. The wound should be assessed and cleansed thoroughly, using proper debridement as indicated. While there are several topical antimicrobial agents that can be used on the infected wound, there is little data on topical treatment. Therefore, such therapy at present can only be considered adjunctive to systemic antimicrobial therapy.

The wound should be managed according to principles discussed previously. Most importantly, the patient should be reassessed within 48 to 72 hours. If no improvement is noted, hospitalization with intravenous antibiotics should be considered. Management of this type of infection should also include close monitoring of the patient's hyperglycemia and general health status. Patient compliance as well as a reduction in the pressure of the infected limb must be considered early on in the treatment of any diabetic foot infection.

Treatment of Limb-Threatening Infections

By definition, limb-threatening infections are much more serious and more often acute compared with the milder non-limb-threatening infections. In the PEDIS system (Table 10 in the original guideline document), limb-threatening infections are classified as grade 3 or 4, depending on severity and the presence of systemic manifestations. Neuropathy often predisposes such infections to progression to an emergent situation before the patient even becomes aware of the infection's presence. Limb-threatening infections may have life-threatening complications, especially when left untreated. Because of diabetes-associated immunosuppression, up to 50% of patients with limb-threatening infections may exhibit no systemic symptoms or leukocytosis. However, other patients present with evidence of systemic toxicity, including fever, chills, loss of appetite, and malaise. Such findings in diabetic patients should alert the clinician to the potential severity of infection. Most will note uncontrollable hyperglycemia despite usual therapy and a loss of appetite.

Limb-threatening infections are recognized as having one or more of the following findings: greater than 2 cm of cellulitis around an ulcer, lymphangitis, soft-tissue necrosis, fluctuance, odor, gangrene, osteomyelitis. When such an infection is recognized, the patient requires emergent hospital admission for appropriate intervention. Upon admission, a complete history and physical examination are undertaken. The patient's cardiovascular, renal, and neurologic risks should be evaluated to assess for secondary complications of diabetes and associated comorbidities. A thorough foot evaluation is undertaken to determine the clinical extent of the infectious process. Vascular status must be assessed to ensure adequate arterial inflow is present. If perfusion is inadequate, this should be addressed prior to definitive reconstruction to enhance healing at a more distal level.

Radiographs are necessary to evaluate for evidence of osteomyelitis or soft-tissue gas. If gas is identified in the ankle or hindfoot, radiographs of the lower leg should be obtained to assess the extent of the gas formation. Blood cultures are required if clinical finding indicate septicemia. Other appropriate laboratory studies, including complete blood count (CBC) with differential and sedimentation rate, should be obtained as warranted. Glucose management must be initiated to optimize metabolic perturbations and to improve leukocyte function. The patients' nutritional and metabolic status must be assessed and properly maintained since such relatively common nutritional and metabolic impairments in these patients can adversely affect wound healing and resolution of infection.

Consultations are typically required in the risk assessment and management of these complex cases. Medical, endocrinology, cardiology, nephrology, and diabetic teaching nurse consultations are often routinely necessary to optimize patient care and fully assess surgical risks. Infectious disease and vascular surgery consultations are also obtained when complex infections or significant ischemia are identified, respectively. A multidisciplinary approach to the management of these cases has been shown to significantly improve outcomes.

Early surgical treatment of the affected site is typically necessary as an integral part of infection management. This may include simple debridement of the soft tissues, wide incision and drainage of the pedal compartments, or open amputation to eliminate extensive areas of infection. At the time of debridement, aerobic, anaerobic, and fungal tissue cultures should be obtained from the depth

of the wound to provide reliability. Although many initial drainage procedures can be done at the bedside for neuropathic patients, most require thorough debridement in the operating room. Anesthesia for such interventions may include local, regional, or general anesthetics. However, spinal blocks are typically avoided in patients who may be septic.

Even the sickest of patients should be considered for emergent incision, drainage, and debridement procedures, because their illness in this regard is directly attributable to the infection severity. Such life-threatening infections necessitate immediate surgical attention, without delay in obtaining radiologic or medical work-up of other comorbid conditions. Polymicrobial infection should be anticipated in these patients (see Figure 9 in the original guideline document), with a variety of gram-positive cocci, gram-negative rods, and anaerobic organism predominating. Accordingly, empirical antibiotic therapy typically includes broad-spectrum coverage for more common isolates from each of these three categories (see Table 11 in the original guideline document). Fully comprehensive empiric coverage is usually unnecessary unless the infection is life-threatening.

Hospital therapies are usually initiated with intravenous medications, although most oral fluoroquinolones and oral linezolid have the same bioavailability as parenteral therapy. Once wound culture results become available, the initial antimicrobial therapy may require adjustment to provide more specific coverage or provide therapy against resistant organisms causing persisting infection. Recent evidence also supports the efficacy of initial parenteral therapy followed by the appropriate oral agent in the management of these patients. If the patient develops evidence of recurrent infection while receiving antibiotic therapy, repeat cultures should be obtained to assess for superinfection. Methicillin-resistant staphylococci, which have emerged as important pathogens in chronically treated diabetic foot ulcer patients, must be detected early and treated appropriately to avoid further tissue loss or extension of infection.

The surgical wound may require repeated surgical debridements to completely eradicate infection and soft-tissue necrosis. Wound care is initiated on day 1 or day 2 postsurgery and may initially involve saline gauze dressing changes. Other dressings may be used to aid in healing. Negative pressure wound therapy (V.A.C. ®, KCI, San Antonio, TX) has been found particularly useful in this regard. If the wound fails to show signs of healing, the patient's vascularity, nutritional status, infection control, and wound off-loading must be re-evaluated.

Once soft-tissue infection is under control and management of any osseous infection has been initiated, consideration may be given to wound closure or definitive amputation. Restoration and maintenance of function and independence is the ultimate goal for the patient. The residual extremity requires close follow-up, regular diabetic foot exams, periodic foot care, and appropriate footwear therapy.

Osteomyelitis and joint infection (see Figure 11 in the original guideline document), when identified by clinical assessment or imaging studies, require a sampling of bone for microbiologic and histopathologic evaluation. If the patient's soft-tissue infection is controlled, consideration may be given to stopping antibiotic therapy 24 to 48 hours presurgery to improve culture accuracy. A diagnosis of osteomyelitis requires that both culture and biopsy studies reveal

positive findings, including necrosis, chronic inflammatory infiltrates, and positive isolation of bacteria. Resection of infected bone with or without local amputation and concurrent antimicrobial therapy is the optimal management for osteomyelitis. However, the routine need for surgery in this condition has recently been questioned. In some cases, based on patient morbidity or preferences, medical therapy alone for osteomyelitis might be warranted. If the affected bone has been completely resected or amputated, the infection may be treated as a soft-tissue infection. However, if residual bone is present in the wound, the patient will likely require 4 to 8 weeks of antibiotic therapy based on the culture results.

Intravenous or oral agents may be used depending on the microbial isolates and the infection severity. Antibiotic impregnated bone cement has been advocated for treatment of osteomyelitis but it should only be used if the bone has been thoroughly debrided and the soft-tissue envelope is adequate for wound closure following antibiotic-impregnated bead placement. Gentamicin, tobramycin, or vancomycin are typically used in the beads. It is generally recommended that the antibiotic beads be removed 2 weeks or so after placement. An alternative to bone cement is absorbable bone graft substitutes mixed with antibiotic powder. The pellets are gradually resorbed as the antibiotic is eluted, thus offering the advantage of avoiding a second operation for removal. While widely used in this regard, studies are lacking as to the efficacy of either modality compared with systemic antimicrobial therapy alone. If the infection fails to respond to therapy, the patient should be fully reassessed as previously discussed.

Diabetic Charcot Foot (Neuropathic Osteoarthropathy) (Pathway 5)

Refer to the original guideline document for definition, etiology, and classification of Charcot foot.

Clinical Diagnosis of Acute Charcot Neuropathic Osteoarthropathy

The initial diagnosis of acute Charcot arthropathy is often clinical, based on profound unilateral swelling, increased skin temperature, erythema, joint effusion, and bone resorption in an insensate foot. These characteristics in the presence of intact skin are often pathognomonic of acute neuroarthropathy. In more than 75% of cases, the patient will present with some degree of pain in an otherwise insensate extremity. The diagnosis is complicated by the fact that in some cases, patients first present with a concomitant ulceration which raises questions of potential contiguous osteomyelitis.

If the patient presents with a warm, edematous, erythematous, insensate foot, plain radiographs are invaluable in ascertaining the presence of osteoarthropathy. In most cases, no further imaging studies will be required to make the correct diagnosis. With a concomitant wound, it may be difficult to differentiate acute Charcot arthropathy from osteomyelitis using plain radiographs alone. Additional laboratory studies may prove useful in arriving at a correct diagnosis. The white blood cell count (WBC) with a left shift will often be elevated in acute osteomyelitis, although this can be blunted in diabetic patients. While the erythrocyte sedimentation rate and C-reactive protein level may also be elevated in acute infection, they often respond similarly to any inflammatory process and are therefore nonspecific. Bone biopsy, when indicated, is the most specific

method of distinguishing osteomyelitis from osteoarthropathy in these circumstances. A biopsy consisting of multiple shards of bone and soft tissue embedded in the deep layers of synovium is pathognomonic for neuropathic osteoarthropathy.

Technetium bone scans are generally nonspecific in assisting in the differentiation between osteomyelitis and acute Charcot arthropathy. Indium scanning, while more expensive, has been shown to be more specific. Additional studies to aid in differentiating osteoarthropathy from osteomyelitis include bone scans utilizing Tc-HMPAO-labeled white blood cells, MRI, and PET scanning.

Other serologic markers can be helpful for the diagnosis of acute Charcot osteoarthropathy. A marker for increased osteoclastic activity, 1CPT (carboxyterminal telopeptide of type 1 collagen), has been shown to be elevated but occurs without increased levels of procollagen carboxyterminal propeptide (P1CP), a marker for osteoblastic activity. Nonetheless, the most important diagnostic aid in this situation remains a high index of clinical suspicion when a neuropathic patient presents with a swollen or deformed foot.

Management of Acute Charcot Neuropathic Osteoarthropathy

Immobilization and stress reduction are the mainstays of treatment for acute Charcot arthropathy. Many clinicians advocate complete non-weightbearing through the use of crutches or other assistive modalities during the initial acute period. While this is an accepted form of treatment, three-point gait may, in fact, increase pressure to the contralateral limb, thereby predisposing it to repetitive stress and ulceration or neuropathic fracture. A short leg plaster or fiberglass non-weightbearing cast can additionally be used for acute Charcot events, even in patients with noninfected ulcerations. A soft compressive dressing in concert with a removable cast walker or pneumatic walking brace can also be used effectively in this regard. Some centers prefer to initially apply a weightbearing total contact cast in the management of acute osteoarthropathy. These ambulatory total contact casts should be changed at least every 1 to 2 weeks to adjust to limb volume changes as the edema decreases.

Following the initial period of off-loading, reductions in skin temperature and edema indicate the stage of quiescence, at which point the patient progresses into the post-acute phase of treatment. Progression to protected weightbearing is permitted, usually with the aid of an assistive device. Through the use of appropriately applied total contact casts or other off-loading modalities (e.g., fixed ankle, walker, bivalved casts, total contact prosthetic walkers, patellar tendon-bearing braces), most patients may safely ambulate while bony consolidation of fractures progresses. Charcot restraint orthotic walkers (CROW) or other similar total contact prosthetic walkers have gained acceptance as useful protective modalities for the initial period of weightbearing. A more readily available option is a pneumatic walking brace or similar removable cast walker that might incorporate a cushioned foot bed or insole. These "instant total contact casts" are made nonremovable by simply applying tape or a fiberglass cast roll around the body of the walker to help encourage compliance.

The mean time of rest and immobilization (casting followed by removable cast walker) prior to return to permanent footwear is approximately 4 to 6 months.

Custom full-length inserts and comfort or extra-depth shoes should be worn when protective bracing is no longer required. Moderately unstable ankles will benefit from an ankle foot orthosis (AFO) and high-top therapeutic shoe, while a severely unstable or maligned rearfoot will require a patellar tendon-bearing (PTB) brace incorporated into a custom shoe. The PTB brace has reportedly decreased mean rearfoot peak forces by at least 32%.

There is recent interest in the adjunctive use of bisphosphonate therapy in acute Charcot arthropathy to help expedite conversion of the acute process to the quiescent, reparative stage. Similarly, electrical bone growth stimulation has been applied to the management of acute neuroarthropathy to promote rapid consolidation of fractures. Low-intensity pulsed ultrasound (LIPUS) has also been suggested as a useful adjunct in promoting healing of Charcot fractures. Although promising in theory, none of these adjunctive treatments have yet been conclusively proven effective through large prospective multicenter, randomized trials.

Surgical Management Of Charcot Osteoarthropathy

Reconstructive surgery may be considered if a deformity or instability exists that cannot effectively be controlled or accommodated by immobilization and off-loading. If the neuroarthropathy is identified in its early stages and non-weightbearing is instituted, surgery is usually unnecessary. According to consensus opinion, surgery in the acute stage is generally nonadvisable due to the extreme hyperemia, osteopenia, and edema present. However, surgical intervention during the acute phase may be considered in the presence of acute subluxation without osteochondral fragmentation. Refer to the original guideline document for further discussion of reconstructive surgery.

The goal of any surgery undertaken on the acute or chronic Charcot foot is to create a stable, plantigrade foot that may be appropriately accommodated. Most operations on chronic Charcot feet consist of exostectomies for prominent plantar ("rocker-bottom") deformities causing ulceration when the remainder of the foot is stable. However, more complex arthrodesis procedures are performed with increasing frequency and success, often using circular external fixation or intramedullary nails. These include isolated or multiple midfoot (see Figure 15 in the original guideline document) or hindfoot fusions, triple arthrodeses, tibiocalcaneal fusions (see Figure 16 in the original guideline document) and ankle fusions.

Following surgery, patients are immobilized until skin temperatures and postoperative edema normalize. As with patients treated nonsurgically, after prolonged cast immobilization patients transition to a removable cast walker followed by permanent prescription footwear or bracing. Mean time from surgery to therapeutic shoes has been reported to be about 27 weeks (7 months). Careful patient selection and management is the rule with these complex diabetic patients since amputation can be a complication of failed surgical procedures.

Surgical Management of the Diabetic Foot (Pathway 6)

Surgical management of the diabetic lower extremity can be a daunting task, but with appropriate patient and procedural selection, successful resolution of

ulceration and correction of inciting pathology may be achieved. Diabetic foot surgery performed in the absence of critical limb ischemia is based on three fundamental variables: presence or absence of neuropathy (LOPS), presence or absence of an open wound, and presence or absence of acute limb-threatening infection.

Classifications of Surgery

Surgical intervention has previously been classified as curative, ablative, or elective. More recently, a modification of this scheme has been proposed that encompasses more procedures and a broader spectrum of patients, as follows:

Class I: *Elective* foot surgery (performed to treat a painful deformity in a patient without loss of protective sensation)

Class II: *Prophylactic* foot surgery (performed to reduce risk of ulceration or re-ulceration in patients with loss of protective sensation but without open wound)

Class III : *Curative* foot surgery (performed to assist in healing an open wound)

Class IV: *Emergent* foot surgery (performed to arrest or limit progression of acute infection)

For any of these classes, the presence of critical ischemia should prompt a vascular surgical evaluation to consider the urgency of the procedure and possible revascularization prior to or subsequent to the procedure.

See the original guideline document for a more detailed discussion of the surgical classifications.

Amputation Considerations

Amputation, a well recognized consequence in the management of the diabetic foot, is performed for a variety of reasons and can be characterized as curative or emergent. Indications for amputation include removal of gangrenous or infected tissue, often to control or arrest the spread of infection; removal of portions of the foot that frequently ulcerate; and creation of a functional unit that can accommodate either normal or modified shoe gear.

In general, the amputation should be performed at a level that balances preservation of limb length and function with the capacity for the surgical site to heal primarily. Although this concept is intuitive, several factors may influence the selection of the level of amputation. It is well recognized that energy expenditure increases as the level of amputation becomes more proximal. Simple tasks such as ambulating to the bathroom or other activities of daily living become increasingly more difficult for the patient commensurate with the level of amputation. In addition, patients with more proximal amputations are far more difficult to rehabilitate to a functional community or household.

Recent advances in vascular surgery have enabled the level of amputation to become more distal or "limb sparing." The capacity to re-establish distal perfusion

with endovascular techniques or bypass surgery to the distal tibial, peroneal, and pedal arteries has greatly enhanced the potential for more distal amputation. In most circumstances, patients should be given the opportunity for vascular surgical intervention prior to definitive amputation so that the most distal level of amputation can be successful.

Goals of Selection of Amputation Level

The selection of the level of amputation should incorporate the following goals:

- Creation of a distal stump that can be easily accommodated by a shoe insert, orthotic device, modified shoe gear, or prosthesis
- Creation of a distal stump that is durable and unlikely to break down from exogenous pressure
- Creation of a distal stump that will not cause muscle or other dynamic imbalances. Examples include medial migration of the lesser digits after 1st MTP joint disarticulation; varus deformity and lateral overload after 5th ray resection; and equinus contracture after transmetatarsal or Chopart amputation.
- Healing with primary intention. In most instances it is advisable to perform an amputation at the most distal level that would allow for primary healing. Unfortunately, there are few objective tests or strategies that can consistently and reliably predict healing potential.

The cost of failure of an amputation at a given level is multifaceted. Increased costs associated with a more proximal level of amputation involve hospitalization, surgical procedures, prostheses, and psychological effects on the patient. It is difficult to stratify the importance of each of these parameters; each should be given consideration before any amputation.

Curative Versus Emergent Surgery

Although it is usually preferable to perform the amputation in an elective, controlled environment, this is not always possible or prudent. When infection, necrotizing fasciitis, or gas gangrene are present, an open amputation may need to be done on an emergent basis (see Figure 19 in the original guideline document). Prior to the definitive amputation, residual infection and ischemia can be addressed. When performed under elective and stable conditions, the amputation should be fashioned so that it is curative. This generally means that the primary incision site can be closed primarily and that no further surgery is anticipated. With primary or even secondary wound healing, the patient can then be fitted for appropriate shoe gear or walking aids. When performed under emergent conditions, the procedure should usually be done proximal to the level of all necrotic tissue. It is anticipated that additional surgical procedures will be necessary to attain a closed wound and a stump that can accommodate shoes, custom inserts, or a prosthesis.

Amputation prevention strategies are identical to those employed for preventing ulceration and have previously been discussed (see Figure 20 in the original guideline document). Prevention is best facilitated through a multidisciplinary approach that focuses not only on the aggressive management of diabetic foot lesions or infections, but also on periodic screening of all diabetic patients, regular

surveillance of high-risk persons, education on risk factors and daily foot care, and provision of therapeutic footwear for patients with a history of ulceration, ischemia, or structural deformities.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Pathway #1: Diabetic Foot Disorders
- Pathway #2: Diabetic Peripheral Arterial Disease
- Pathway #3: Diabetic Foot Ulceration
- Pathway #4: Diabetic Foot Infection
- Pathway #5: Charcot Foot
- Pathway #6: Surgery of the Diabetic Foot

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is not specifically stated for each recommendation.

This clinical practice guideline is based on the consensus of current clinical practice and review of the clinical literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Foot care programs emphasizing preventive management can reduce the incidence of foot ulceration through modification of self-care practices, appropriate evaluation of risk factors, and formulation of treatment protocols aimed at early intervention, limb preservation, and prevention of new lesions. The foot and ankle surgeon should play an integral role in this scheme, providing ongoing surveillance, education, and management of new or impending lesions. A significant reduction in both major and minor diabetic limb amputations is certainly attainable if clinicians embrace these principles and incorporate them into daily patient care.

POTENTIAL HARMS

- As a diagnostic vascular procedure, ankle-brachial indices may be misleading since ankle pressures can be falsely elevated due to medial arterial calcinosis and noncompressibility of affected arteries.
- Amputation can be a complication of failed surgical procedures

CONTRAINDICATIONS

CONTRAINDICATIONS

- A list of contraindications to specific types of dressings and topical therapies/agents used in wound management can be found in Table 8 of the original guideline document.
- Debridement may be contraindicated in arterial ulcers.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

While these guidelines cannot and should not dictate the care of all affected patients, they provide evidence-based guidance for general patterns of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, Landsman AS, Lavery LA, Moore C, Schuberth JM, Wukick DK, Andersen C, Vanore JV. Diabetic foot disorders: a clinical practice guideline. J Foot Ankle Surg 2006 Sep-Oct;45(5):S2-66. [579 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Sep (revised 2006 Sep)

GUIDELINE DEVELOPER(S)

American College of Foot and Ankle Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Development and publication of this Clinical Practice Guideline was made possible by an educational grant co-sponsored by Johnson & Johnson Wound Management, a division of ETHICON, INC. and KCI USA, Inc.

GUIDELINE COMMITTEE

Clinical Practice Guideline Diabetes Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Robert G. Frykberg, DPM, MPH; Thomas Zgonis, DPM; David G. Armstrong, DPM, PhD; Vickie R. Driver, DPM, MS; John M. Giurini, DPM; Steven R. Kravitz, DPM; Adam S. Landsman, DPM, PhD; Lawrence A. Lavery, DPM, MPH; J. Christopher Moore, DPM; John M. Schuberth, DPM; Dane K. Wukich, MD; Charles Andersen, MD; and John V. Vanore, DPM

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons. J Foot Ankle Surg 2000;39(5 Suppl):S1-60. [248 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Foot and Ankle Surgeons (ACFAS) Web site.

Print copies: Available from the American College of Foot and Ankle Surgeons, 515 Busse Highway, Park Ridge, IL 60068-3150; Web site: www.acfas.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- A screening tool for use with a diabetic foot evaluation is available in Appendix 1 of the original guideline document.

Print copies: Available from the American College of Foot and Ankle Surgeons, 515 Busse Highway, Park Ridge, IL 60068-3150; Web site: www.acfas.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 31, 2001. It was reviewed by the guideline developers as of March 11, 2002. This NGC summary was updated by ECRI on December 29, 2006. The updated information was verified by the guideline developer on January 8, 2007. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/15/2008